

October 24, 2013

Ms. Kimberly Nesci
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application

- Spexit
- Andermatt Biocontrol AG

Dear Ms. Nesci:

On behalf of Andermatt Biocontrol AG, SciReg, Inc. is submitting a new product registration application for Spexit, an end-use product containing 0.6% *Spodoptera exigua* multinucleopolyhedrovirus (SeMNPV), strain BV-0004. In support of this application, Andermatt is submitting generic and product-specific data and information, and citing existing SeMNPV data.

As agreed during the April 23, 2013 preregistration meeting and reiterated in the associated meeting minutes (attached), below is a discussion of the submitted data and the associated active ingredient.

Currently, there is one EPA-registered product that contains SeMNPV, Spod-X LC (EPA Reg. No. 70051-46).

The following characteristics of baculoviruses are outlined in OECD Consensus Document No. 20 (submitted herein), which was developed under the OECD Working Group on Biotechnology.

- Baculovirus species are extremely host-specific, with their host range limited to one or a few species of the same genus. Larger host ranges covering different genera or even different families are rare. Baculoviruses probably represent the most specific pesticidal agents, biologicals and chemicals taken together.

SciReg, Inc.
Science and Regulatory Consultants

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- Baculoviruses occur only in arthropods, predominantly in the insect orders *Lepidoptera*, *Diptera*, and *Hymenoptera*.
- Baculoviruses are not infective to mammals and replication does not occur in mammalian cells.
- No pathogenic, genotoxic, mutagenic, or carcinogenic effect of baculoviruses has ever been observed in mammals.
- Baculoviruses do not produce metabolites since they have no independent metabolism.
- Effects on non-target species can be excluded, especially for vertebrates, micro-organisms, and plants.

It is thoroughly established that baculoviruses are neither toxic, nor pathogenic. Andermatt Biocontrol is, therefore, submitting and citing data and information on SeMNVPV, as well as other baculoviruses, in support of its registration of Spexit.

As there is an existing tolerance, 40 CFR Part 180.1118, for occlusion bodies of the nuclear polyhedrovirus of *Spodoptera exigua* and, as such, although the proposed product will be used on food crops and is considered to contain a new active ingredient, it was determined during the preregistration meeting that this regulatory action falls under PRIA Category B612 – New active ingredient; no change to a permanent tolerance exemption. The corresponding PRIA fee is \$16,714. Andermatt qualifies for a 50% PRIA fee reduction; supporting company and financial information is included herein. A copy of the electronic payment receipt for \$8,357.00 is enclosed.

If you have any questions regarding the application materials, please let me know.

Sincerely,



Patricia Biggio
Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Andermatt Biocontrol AG
Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

SciReg, Inc. *
12733 Director's Loop
Woodbridge, VA 22192

* SciReg, Inc. is the authorized agent for Andermatt Biocontrol AG.

Regulatory action in support of which this package is submitted

New Product Registration: Spexit

Transmittal Date

October 24, 2013

Contents

Volume 1	Administrative Materials
49238701 Volume 2	Product Identity, Manufacturing Process, Deposition of a Sample in a Nationally Recognized Culture Collection, and Discussion of the Formation of Unintentional Ingredients (OCSPP 885.1100, 885.1200, 885.1250, and 885.1300)
49238702 Volume 3	Analysis of Samples and Certified Limits (OCSPP 885.1400 and 885.1500)
49238703 Volume 4	Summary of the Physical-Chemical Properties (OCSPP 830.6302 - 830.7300)
49238704 Volume 5	Physical and Chemical Characteristics: Color, Physical State, Odor, Storage Stability, Corrosion Characteristics (OCSPP 830.6302, 830.6303, 830.6304, 830.6317, 830.6320)
49238705 Volume 6	Physical and Chemical Characteristics: pH, Viscosity, and Density (OCSPP 830.7000, 830.7100, and 830.7300)
49238706 Volume 7	Hypersensitivity incidents (OCSPP 885.3400)
49238707 Volume 8	Nontarget Organism Waiver (OCSPP 885.4100, 885.4150, 885.4280, 885.4300)

Company Official: Patricia Biggio



Company Name: SciReg, Inc.

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